UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------X

THE ORIGINAL CREATINE PATENT COMPANY, LTD.,

Plaintiff,

- against -

MET-RX USA, INC.,

Defendant.

----------X

REPORT AND RECOMMENDATION

CV 05-2244 (DRH) (JO)

JAMES ORENSTEIN, Magistrate Judge:

Plaintiff The Original Creatine Patent Company, Ltd. ("OCPC") accuses defendant Met-RX USA, Inc. ("Met-RX") of direct and indirect infringement of two patents in violation of 35 U.S.C. § 271(a)-(b). *See* Docket Entry ("DE") 47 ("Amended Complaint"). Before the court can determine the merits of the complaint, it must first construe the relevant terms of the patents at issue, three of which are in dispute. *See generally Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). On March 2, 2006, the honorable Dennis R. Hurley, United States District Judge, referred the matter to me to conduct a *Markman* hearing. Having held such a hearing and reviewed the parties' many submissions, I now make my report and, for the reasons set forth below, respectfully recommend that the court adopt the following interpretations:

- In claim 1 of the 159 Patent, as Met-RX contends, the term "suffering from or running a risk of depletion of muscle phosphoryl creatine storage" means "having reduced, or potentially reduced, phosphoryl creatine storage in muscle;"

- In claim 1 of the 159 Patent, as OCPC contends, the term "not less than an amount corresponding to 15g creatine in a 70 kg mammal" requires no construction beyond its plain terms;

- In claim 17 of the 544 Patent, as Met-RX contends, the term "unitary doses" means "10-20 grams of creatine composition that are individually packaged in sachets, bags, packets, cylinders, bottles, or other suitable packages."

I. Background

A. The Patents-In-Suit

OCPC is an English patent-holding company that acquired its interest in the patents at issue from their respective inventors. Amended Complaint ¶¶ 2, 6, 7. Met-RX is a Nevada-based corporation that develops and manufacturers sports nutrition products. DE 49 (Answer to Amended Complaint) ¶ 3; DE 68-1 (Met-RX's Opening Claim Construction Brief) ("MB") at 2. At issue in this litigation are two patents: U.S. Patent No. 5,767,159 (filed July 15, 1993) (the "159 Patent") and U.S. Patent No. 5,968,544 (filed May 30, 1997) (the "544 Patent"). *See* DE 63-2 (copy of 159 Patent); DE 63-3 (copy of 544 Patent). Both relate to the use as a dietary supplement of creatine, a compound that the human body naturally produces and stores in skeletal muscle and the depletion of which contributes to muscle fatigue. The 159 Patent, which concerns a method for increasing the body's supply of creatine to improve muscle performance, was issued on June 16, 1998, to co-inventors Eric Hultman and Roger C. Harris ("Harris"). The 544 Patent, which concerns a creatine-based composition for human consumption and a method of providing the same, was issued on October 19, 1999, to co-inventors Harris and Alan Norman Howard.

The inventors were neither the first to discover creatine nor the first to patent a creatine composition or a process for administering one. Creatine was apparently discovered in the nineteenth century and, as discussed in the 159 Patent, there is a considerable amount of prior art concerning the administration of creatine and its derivatives. *See* Paul L. Greenhalf, *Creatine: Its Role in Physical Performance and Fatigue and its Application as a Sports Food Supplement*, Insider, March 1995, at 1 (reprinted in DE 68-2 Ex. 1); 159 Patent col.1 l.58-col.2 l.43.

1. The 159 Patent

The invention claimed in the 159 Patent is, in essence, a method for administering creatine in a manner that increases the creatine content in muscle tissue to achieve improved muscular strength and functioning. *See* 159 Patent col.1 ll.4-19 (Description of the Invention). The 159 Patent discloses a number of prior patents claiming inventions that use creatine-related ingredients in various medical and veterinary treatments. The disclosed inventions include: creatine in its phosphorylated form, or phosphocreatine, as an ingredient in treatments for cardiac disease and ischemic tissue; a creatine analog (cyclocreatine) as a treatment for similar conditions in animals; and creatine precursors as a treatment for increasing creatine content in skeletal and cardiac muscle. The patent further cites two articles discussing cyclocreatine and phosphocreatine as treatments for ischemia. *See* 159 Patent col.1 l.58-col.2 l.47. The specification differentiates the claimed invention from such prior art primarily on the ground that the former uses creatine as opposed to phosphocreatine, cyclocreatine, or creatine precursors, which the inventors claim differ in key respects from creatine. *Id*. at col.2 ll.48-64. The inventors also claim that their invention calls for a higher dosage of creatine than is found in prior art: commenting on a number of publications citing the ineffectiveness of creatine therapy, they conclude that the lack of positive results is likely explained by the fact that the amounts of creatine supplied were too low. *Id.* at col.2 ll.65-67.

The 159 Patent specification discusses the utility of the invention. The inventors claim that their method can be used to improve muscle capacity and functioning in patients suffering from a variety of cardiac and respiratory conditions, and to prevent the depletion of phosphoryl creatine stores during intense physical activity. *See id.* col.3 ll.43-50 (Summary of the

Invention). The method itself is best described by reference to the patent's first claim, which is the only one in this patent as to which the parties cannot agree on an interpretation:

> A method for increasing the muscle performing capability in mammals having no disorder in creatine metabolism but suffering from or running a risk of depletion of muscle phosphoryl creatine storage comprising administering daily to said mammals, either enterally or parenterally, at least 0.2 [grams of] creatine [per kilogram of] body weight and not less than an amount corresponding to 15 [grams of] creatine in a 70 [kilogram] mammal.

col.6 ll.19-25 ("Claim 1").

2. The 544 Patent

The 544 Patent concerns creatine compositions for human consumption and a method of providing them in a way that preserves their effectiveness. *See* 544 Patent col.1 ll.5-7. The composition itself is acidic and can be a liquid, semi-liquid, or powder. *See id*. col.2 ll.16-52. The method of administration is described as a means of storing the composition in its liquid form or of supplying it in a powder form that can be mixed with water to create an "isotonic" drink, which the patent defines as a drink that "corresponds to the osmotic potential of human body fluids." *Id*. col.2 ll.35-37, 53-38 & col.3 ll.10-15. The invention concerns both the storage of liquid and semi-liquid compositions and the provision of the composition in its powder form. *Id.* col.2 l.53-col.3. l.39. The only disputed term in this patent concerns the latter. Claim 9, the interpretation of which is not disputed, generally explains this aspect of the invention:

> A stable, dry powder composition comprising creatine, said composition being unflavored or fruit flavored, which, when mixed with water or an aqueous solution, provides an acidic drink for human consumption, said creatine being substantially stable at ambient temperature or below.

Id. col.10 ll.17-21. The disputed term is found in claim 17, which provides: "A composition according to claim 9, provided as unitary doses." *Id.* col.10 ll.43-44.

B. Procedural Background

OCPC initially filed suit against Met-RX in the Eastern District of Virginia on December 20, 2004, with a complaint raising a single claim of indirect infringement of the 159 Patent. *See* DE 21-2 (Complaint). More specifically, that complaint accused Met-RX of "actively and willfully inducing others to infringe ... the 159 Patent through its making, using, selling and offering to sell of creatine-containing products" such as "Met-RX's 'Micronized Creatine.'" *Id.* ¶ 7. On February 22, 2005, Met-RX submitted an answer denying all of OCPC's allegations. DE 21-3. On the same date, it also moved to transfer the case to this court. DE 21-8. The court granted that motion and the case was transferred to this court on May 4, 2005. *See* DE 21-1.

On September 27, 2005, OCPC filed an amended complaint in this court that raises both the indirect infringement claim discussed above and an additional claim of direct infringement of the 544 Patent. The latter claim alleges that Met-RX "has made, used, offered for sale and/or sold, and continues to make, use, sell and/or offer for sale, creatine-containing products" that infringe the 544 Patent. Amended Complaint ¶ 8. Met-RX's answer to that complaint denies all of these allegations and raises seven affirmative defenses and two counterclaims. *See* DE 49. The crux of both the counterclaims and of two of the affirmative defenses is Met-RX's contention that both of the patents at issue in this litigation are invalid. *See id*. at 3, 5.[1]

[1] The remaining affirmative defenses are based on theories of laches, estoppel, and an assertion that OCPC failed to meet the pleading requirements of 35 U.S.C. §§ 283-284. *Id*. at 3-4. Met-RX later amended its answer to assert additional affirmative defenses and counterclaims related to the alleged unenforceability of each patent. *See* DE 83-2 ¶¶ 15-71.

The parties submitted their first joint claim construction statement on January 5, 2006, and first filed their claim construction briefs on January 20, 2006.[2] I conducted the *Markman* hearing on April 28, 2006. At that hearing it became apparent that the disputes between the parties regarding the proper interpretation of the patents were significantly narrower than their papers suggested. I therefore directed the parties' respective counsel to meet and confer and then report back to me as to which of the patents' claim terms, if any, actually remained in dispute. *See* DE 108. The parties subsequently timely filed a second claim construction statement and reported that while they had agreed on definitions for several terms, they had also identified one additional disputed term. *See* DE 109 (Second Joint Claim Construction Statement) ("JCCS II"). They subsequently filed supplemental briefs on the construction of that term. *See* DE 110 (Met-RX's Supplemental Brief) ("MS"); DE 112 (OCPC's Supplemental Brief) ("OS").

There are thus three disputed patent claim terms. Two of the disputed terms are found in the first claim of Patent 159, which I quote in full with the disputed terms highlighted in italics:

> A method for increasing the muscle performing capability in mammals having no disorder in creatine metabolism but *suffering from or running a risk of depletion of muscle phosphoryl creatine storage* comprising administering daily to said mammals, either enterally or parenterally, at least 0.2 g creatine/kg body weight and *not less than an amount corresponding to 15 g creatine in a 70 kg mammal*.

159 Patent col.6 ll.19-25 (emphasis added). The third disputed term appears in claim 17 of the 544 Patent (again with the disputed words highlighted in italics): "A composition according to claim 9, provided as *unitary doses*." 544 Patent col.10 ll.43-44 (emphasis added).

---

[2] Those documents included, in addition to documents cited above, the parties' initial Joint Claim Construction Statement, DE 56 ("JCCS I"); OCPC's Opening Claim Construction Brief, DE 62 ("OB"); Met-RX's Reply Brief, DE 74 ("MR"); and OCPC's Reply Brief, DE 72 ("OR"). OCPC subsequently submitted a revised version of its reply memorandum of law that corrected certain typographical errors. *See* DE 105-106.

II. Discussion

A. Legal Principles

The scope of a patentee's invention, and thus also the scope of the patentee's right to exclude others from using or replicating it, derive from the numbered paragraphs at the end of the patent commonly known as the patent claims. *See Astrazeneca AB v. Mutual Pharmaceutical Co.,* 384 F.3d 1333, 1336 (Fed. Cir. 2004). The first step in any patent infringement analysis is claim construction: the process by which the court interprets the terms of the patent's claims in order to "define the scope of the patentee's rights." *Markman*, 52 F.3d at 970-971 (Fed. Cir. 1995); *see also Netword LLC v. Centraal Corp.,* 242 F.3d 1347, 1352 (Fed. Cir. 2001) ("'Claim construction' is the judicial statement of what is and is not covered by the technical terms and other words of the claims.").

Claim construction is governed by a series of well-settled principles. First, "the words of a claim are generally given their ordinary and customary meaning." *Philips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotations omitted). The ordinary and customary meaning of a claim term is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id*. at 1313. To determine a given term's ordinary and customary meaning, the court should look to those publicly available sources from which one skilled in the art would have interpreted the claim language. *See Innova/Pure Water, Inc. v. Safari Walter Filtration Systems, Inc.,* 381 F.3d 1111, 1116 (Fed. Cir. 2004). These sources fall into two categories: "intrinsic" evidence, which consists of the actual claim text, the specification, and the prosecution history; and "extrinsic" evidence such as expert testimony, dictionaries, and treatises. *See id*. (citing *Markman*, 52 F.3d at 979-980).

In *Philips*, the court explained how to weigh these different types of evidence. First, the court emphasized the primacy of the actual claim language and the context in which claim terms are used. *See* 415 F.3d at 1314 ("the claims themselves provide substantial guidance as to the meaning of particular claim terms"). It also noted, however, that claim terms must always be read with an eye towards the specification, which is "'highly relevant'" and "'usually dispositive.'" *See id.* at 1315 (quoting *Vitronics*, 90 F.3d at 1582). The specification's significance to claim construction is traceable to the patent statute, which requires that the specification describe the invention "'in full, clear, concise, and exact terms.'" *See id.* at 1316 (quoting 35 U.S.C. § 112, ¶ 1). Next, the court noted the relevance of the prosecution history when it is in evidence, but cautioned that this is necessarily "less useful" than the specification because the former "represents an ongoing negotiation" whereas the latter represents "the final product of that negotiation." *Id.* at 1317. With respect to extrinsic evidence like expert testimony and treatises, the court noted that it can provide useful and reliable guidance under some circumstances, but also noted that such evidence is generally not specific to the patent at issue and thus rarely offers insight into a patent's scope that is comparable to intrinsic evidence. *Id.* at 1317-1318. Accordingly, the court expressly held that extrinsic evidence is "'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Id*. at 1318 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). With these principles in mind, I turn to the parties' disputes about three specific claim terms.

B. "Suffering From Or Running A Risk Of Depletion Of Muscle Phosphoryl Creatine Storage" (159 Patent, Claim 1)

OCPC proposes the following narrow construction of the claim term: "suffering from the reduction, or the potential reduction, of phosphoryl creatine storage in muscle *that occurs from intense physical activity*." JCCS II at 2 (emphasis added). It asserts that the patent's specification and prosecution history provide direct support for such an interpretation. OS at 2-5.

Met-RX argues that OCPC's proposal contains a limitation not found in the term's plain language or in its preamble and that it excludes embodiments identified in the specification by improperly limiting the claim to a preferred embodiment. MS at 2-5. Accordingly, it advocates a more general construction: "having reduced, or potentially reduced, phosphoryl creatine storage in muscle." JCCS II at 2. As explained below, I share with Met-RX's objection to OCPC's interpolation of a concept not found in the disputed term's text, and concur with the broader alternate proposal.[3]

The text of Claim 1 plainly does not limit the invention with respect to the cause of the actual or potential reduction in phosphoryl creatine storage that it seeks to remedy or avert. Moreover, while OCPC asserts that its construction is necessary to avoid inconsistency with the remainder of the claim, in particular with the term, "increasing ... muscle performing capability," *see* OS at 3, I do not see any inconsistency that necessitates such a limitation. As discussed below, the specification clearly indicates that increasing muscle performing capability is useful

[3] In making this determination, I do not rely on any interpretation of the preamble to Claim 1 ("A method for increasing the muscle performing capability in mammals having no disorder in creatine metabolism"). As a result, I need not and do not address OCPC's complaint that Met-RX, by resting its argument on an implicit interpretation of that prefatory language, has improperly raised an additional claim construction issue. *See* DE 114.

both with respect to the performance of intense physical activity and in treating a variety of medical conditions.

Each party claims support for its proposed definition from the specification. OCPC emphasizes the number of instances in which the inventors refer to "intense physical activity." *See* OS at 3-4. Met-RX emphasizes the discussion enumerating several non-exercise-related embodiments of the invention as well as the many different causes of creatine depletion identified and discussed in the specification. *See* MS at 3-4.

In the specification, "intense physical activity" is consistently cited as only one of several applications for the invention. For example, in a section titled, "Background of the Invention," the invention's use as a treatment to "prevent[] the effects of depletion of the muscle phosphoryl creatine store during intensive activity" appears as one of several separately enumerated applications, only a minority of which are related to intense physical activity and most of which clearly concern the invention's medical applications. Examples of the latter include: "pre-treatment in connection with heart surgery" and treatment for various cardiac and respiratory conditions, malnutrition, fibromyalgia, and muscular disease. 159 Patent col.3 ll.12-19. These medical applications are later expressly referenced in the following discussion, which appears in a section of the specification captioned "Summary of the Invention:"

> The object of the present invention is to provide a cheap, simple and safe preparation, without side effects which can be given to mammals having no disorders in their creatine metabolism. Said preparation can be used in connection with *the disorders identified above* and also to prevent the effects of depletion of the muscle phosphoryl-creatine store during intensive activity and thereby improve the capacity of the muscles and also shorten the recovery phase.

Id. col.3 ll.43-50 (emphasis added). The clear meaning of the quoted language is that the inventors anticipated that their invention could be used to combat the depletion of muscular phosphoryl-creatine stores caused by various pathologies in addition to that caused by strenuous exercise. Finally, in summarizing the many medical and exercise-related objects of the invention, the inventors note that "these objects are important in conditions where energy rich compounds are limiting*, such as post-operative fatigue, respiratory and/or cardiac insufficiency*." *Id*. col.3 ll.56-58 (emphasis added).

In essence, OCPC asks the court to ignore the specification's many explicit and unambiguous references to the invention's non-exercise-related applications. In doing so, it ignores the very different approach embraced by controlling case law. Rather than ignore the plain meaning of the specification's language, I must assume that the inventors intended it to describe their invention and interpret the patent claims in light of that description. *See Philips*, 415 F.3d 1303, 1315-1317 (Fed. Cir. 2005). For that reason, I conclude that Met-RX offers a more faithful interpretation of the specification.

OCPC also cites the patent's preferred embodiment and drawings in support of its proposed interpretation. *See* OS at 3-4. Met-RX argues that OCPC seeks to improperly limit its patent to a preferred embodiment. MS at 4. In light of the patent's express discussion of the invention's potential as a treatment for various medical disorders, I agree.

The preferred embodiment first discusses the effective dose (in essence, the inventors' method claim) and its efficacy in increasing creatine content in muscle tissue. It then discusses several studies that examined the effect of increased muscular creatine concentration on exercise performance. *See* 159 Patent col.4 l.28-col.5 l.5. The first such study measured creatine's effect

on the subjects' performance of five separate weight-lifting exercises. *Id*. col.4 ll.42-54. After one week, the test subjects who had been given creatine had significantly greater increases in measured muscle power relative to those who had been given a placebo. The patent next discusses a series of similar studies examining the effect of creatine at the dosage specified in the invention on thousand-meter runners. *Id.* col.4 l.55-col.5 l.5. The inventors report that runners administered creatine had both faster running times and increased body weight relative to a control group that received a placebo. *Id.*

The patent's five drawings all diagram the creatine content of blood or muscle tissue following creatine supplementation according to the claimed method. *Id.* at 2-6 (Figures 1-5). The first figure illustrates the concentration of creatine in the blood of individuals after the administration of a single dose of 500 milligrams of creatine dissolved in 200 milliliters of warm water. *Id.* at 2; *see id.* col.5 ll.8-12. The remaining four drawings illustrate the level of measured creatine in individuals' leg muscles at certain intervals after specified regimes of creatine supplementation and, in some cases, strenuous exercise. *Id.* at 3-5; *see id.* col.5 l.8-col.6 l.17.

As I interpret the preferred embodiment, it addresses two distinct issues: first, the effectiveness of the invention at increasing creatine content in muscle tissue; and second, the effect of increased creatine content on muscle performance. That the latter concern comprises the bulk of the discussion in the preferred embodiment and the patent's drawings is not a basis for ignoring the fact that, as discussed, the patent generally speaks of several different uses for the claimed method. Although the preferred embodiment focuses on the invention's exercise-related application, in light of the numerous references to the invention's many medical applications throughout the specification, it would be improper to interpret this as a limitation. *See Gilette*

Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1374 (Fed. Cir. 2005) (noting that a specific embodiment that is narrow in scope should not be read to limit unequivocal broad claim language); *see also Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.").

Finally, OCPC claims that the prosecution history provides support for the limitation it proposes. The inventors originally applied for a single patent covering both the method that is claimed in the 159 Patent and the composition claimed in the 544 Patent. The patent examiner severed the method claim from the compound claim because the compound could be used in a materially different process – "for example, the method described by Manchetti et al." *See* JCCS I Ex. C (prosecution history of the 159 Patent submitted in three parts as DE 69, DE 70, and DE 71) ("Prosecution History") at 245.[4] OCPC argues that because the Manchetti process concerns the use of creatine as a treatment for neuromuscular disease, the patent examiner's finding presupposes that the inventors' method claim did not have a neuromuscular disease application. *See* OS at 5.

The prosecution history is too ambiguous on this score to compel the conclusion OCPC draws from it, particularly in light of the unambiguous statement in the 159 Patent's specification about the conditions causing creatine depletion with which it may be used. The patent examiner noted only that the Manchetti process was materially different from that claimed in the then-pending application (which is covered by the 159 Patent). *See* Prosecution History at 245.

---

[4] The pages of the Prosecution History are consecutively numbered from "OCPC 000105" through "OCPC 000334." As a convenient shorthand, I refer to the pages by their last three digits.

OCPC has not introduced any evidence as to how the two differed, and nothing in the record compels me to conclude that the material difference at issue was specifically that Manchetti involves using creatine as a treatment for neuromuscular disease while the method at issue does not. Moreover, even assuming the veracity of OCPC's claim concerning the reference to Manchetti, which I cannot confirm since it is not in the record before me, this would be an insufficient basis on which to read all of the non-exercise applications out of the patent. That the composition, which is not even the subject of the 159 Patent, could be used in other processes is a separate issue from whether the invention at issue was intended for both exercise and medical uses.

OCPC next argues that the prosecution history demonstrates that the patent examiner understood the method to be directed specifically to circumstances involving intensive physical activity. *See* OS at 5. None of the patent examiner's comments that OCPC cites supports that argument. For example, OCPC cites two occasions in which the patent examiner noted that the inventors distinguished their invention from certain prior art (concerning the reduced skeletal muscle performance caused by artificial creatine depletion) on the ground that they called for "creatine supplementation in order to increase muscle performance." Prosecution History at 266; *see id*. at 261. OCPC appears to argue that the reference to increased muscle performance supports its interpretation. I conclude to the contrary that the term is broad enough to encompass the many medical applications that appear in the specification.

Based on the foregoing, I recommend that the court construe the claim term "suffering from or running a risk of depletion of muscle phosphoryl creatine storage" to mean "having reduced, or potentially reduced, phosphoryl creatine storage in muscle."

C. "Not Less Than An Amount Corresponding To 15g Creatine In A 70 kg Mammal" (159 Patent, Claim 1)

Met-RX argues that the intrinsic evidence establishes that the claim's scope is limited with respect to the weight of the mammals for whom the invention applies. Accordingly, it advocates the following construction, which incorporates such a weight restriction: "administering said creatine *only to mammals of at least 70 kg* body weight, in an amount not less than 15 g." *See* MB at 9 (emphasis added). In other words, Met-RX takes the position that the reference to "70 kg" in the disputed claim term renders the patent inapplicable to products used by mammals weighing less than that amount.

OCPC rejects that construction and asserts that this claim term has a plain meaning that is also consistent with the intrinsic evidence. *See* OB at 2; OR at 14-20. I agree: the term plainly establishes a creatine-to-body-weight ratio that reflects the minimum dosage necessary to achieve the desired effect; that ratio does not include or imply a minimum weight restriction on the class of users to whom the product can be administered.

Notably, Met-RX's proposed construction not only adds a weight limitation that the claim itself does not express, it also effectively deletes the words "corresponding to" from the claim. Met-RX faces a significant hurdle in advocating such an atextual construction. Claim language should not be ignored and claim constructions that render claim terms superfluous are strongly disfavored. *See Merck & Co. v. Teva Pharms. USA, Inc.,* 395 F.3d 1364, 1372 (Fed. Cir. 2005) (citing *Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.,* 214 F.3d 1302, 1307 (Fed. Cir. 2000); *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed. Cir. 1996)).

Met-RX first argues that without the weight restriction the claim contradicts the patent specification. *See* MB at 9-10. In particular, they point to the statement in the specification that the inefficacy of creatine therapy discussed in several publications "depends probably on that [sic] the amount as supplied is too low." 159 Patent col.2 ll.65-67. The quoted portion of the specification also contains a list of prior art including a European patent for a muscle-performance-enhancing composition containing "carnosine or peptides related thereto." As an optional active ingredient, that composition may also include daily doses of creatine in amounts ranging from 500 miligrams to ten grams. *See* 159 Patent col.2 ll.16-29. Met-RX seems to argue that construing the patent to apply to mammals weighing less that 70 kilograms creates the possibility that the claimed method will result in a dosage of creatine similar or even identical to an amount that the inventors deem insufficient and ineffective. *See* MB at 9-10.

The argument proves too much. There is no evidence that the publications to which the inventors refer discuss the European patent they earlier cite. Moreover, without more detail about the conditions of the administration of the composition at issue in the European patent – such as, for example, the body weight of the mammals administered ten grams of creatine – there is no foundation for the conclusion that the potential ten gram dosage of creatine as an optional ingredient discussed in it actually overlaps with the invention covered by the 159 Patent.[5] Finally, to the extent Met-RX argues that the claim would be invalid in light of disclaimed prior

[5] For example, the body weight of a mammal administered a ten gram dose pursuant to the undisputed portion of the inventors' method - at least 0.2 grams per kilogram of body weight - could weigh no more than 50 kilograms (110 pounds). *See* 159 Patent col.6 ll.23-24. There is no indication that the European patent at issue calls for the administration of ten grams of creatine to mammals meeting this criterion.

art, I note only that unless a claim term is ambiguous, it is improper for a court to consider validity as a factor in claim construction. *See Philips,* 415 F.3d at 1327.

Met-RX next claims to find support for its interpretation from the specification. Before analyzing what the specification says, it is important to note what it does not say: there is no explicit mention anywhere in the specification of a weight restriction that narrows the class of those who can be administered the invention. In an undisputed portion of Claim 1, the inventors describe the minimum dosage of creatine to be administered as "at least 0.2 [grams of] creatine [per kilogram of] body weight." 159 Patent col.6 ll.23-24. If the specification stated an absolute minimum amount of creatine necessary to achieve the invention's beneficial effect, this would provide some support for reading such a weight restriction into the patent language. However, as will be shown, the specification language is at most ambiguous on this score.

The most relevant portion of the specification is the "Summary Of The Invention," in which the inventors discuss the dosage necessary to achieve the invention's intended effect of increasing creatine content in muscle tissue. They provide four different descriptions of the effective dosage. They first describe it thusly: "enteral or parenteral administration of at least 15 grammes, or 0.2-0.4 g/kg body weight or preferably about 0.3 g/kg body weight, per day of creatine over at least 2 days." 159 Patent col.3 ll.64-67.[6] In the next paragraph, the inventors note that "the amounts [of creatine administered] should be not be less than 15 g per day in a 70 kg/subject." *Id.* col.4 ll.5-6. Later, the inventors refer to supplementation of "15 to 30 grammes creatine per day over at least 2 days." *Id.* col.4 ll.7-8. Lastly, the inventors note, "Creatine is

---

[6] Essentially the same language also appears in three other sections of the specification: the abstract, description, and background. *See* 159 Patent Abstract, col.1 ll.11-13, col.3 ll. 4-6.

preferably supplied in an amount of 15 to 30 grammes, or 0.2-0.4 g/kg body weight, per day over 4 to 7 days ...." *Id.* col.4 ll.14-16.

None of these alternate formulations of the effective dose unambiguously sets forth an absolute minimum amount. To the extent that references to 15 grams suggest a minimum dosage, the claim itself clarifies that as an absolute amount to be administered pursuant to the claimed method, 15 grams is only appropriate for mammals of a certain size. Moreover, read together, these various descriptions are more consistent with the concept of a non-weight-restricted creatine-to-body-weight ratio than with an absolute minimum amount.

Met-RX also claims to find support for its proposed weight restriction in the "Preferred Embodiment" section of the specification. *See* MB at 10; MR at 3. First, Met-RX notes that the inventors refer to "'repeated doses of 5 g creatine [sic] ... supplied every day to a 70 kg subject....'" MB at 10 (quoting 159 Patent col.4 ll.28-29). Viewed in context, the passage is plainly illustrative; the reference to "a 70 kg subject" in no way suggests a weight restriction. Met-RX also claims that all of the participants in the studies discussed in this section, the results of which are diagramed on the patent drawings, weighed at least 70 kilograms. Notably, the patent only identifies the weight of the three subjects whose results are plotted on the first drawing; it is unclear what the roughly fourteen other subjects (whose results are diagramed on the other four drawings) weighed either before or after supplementation. *See* 159 Patent at 2-6 (Figures 1-5), col.5 l.8-col.6 l.17. Even assuming OCPC's assertion about the weight of the study subjects to be true, its simply does not advance its argument because it says nothing about the intended scope of the invention. There is simply nothing in the specification to suggest that the claim term should be construed other than as the ratio that its plain language creates.

Each side finds support for its proposed construction in the prosecution history. Met-RX claims that the history pertinent to this claim term establishes the inventors' intent to disclaim the patent's coverage over mammals weighing more than 70 kilograms. *See* MB at 10-13; MR at 5. OCPC argues to the contrary that the prosecution history supports an unrestricted creatine-to-body-weight ratio. *See* OR at 18-20. As a legal matter, it is true that a claim term can be narrowed by an express disclaimer in the prosecution history. *See Philips*, 415 F.3d at 1317. However, such a disclaimer must be "clear and unambiguous." *See Inverness Medical Switzerland GmbH v. Princeton Biomeditech Corp.,* 309 F.3d 1365, 1372-1373 (Fed. Cir. 2002) (citing cases). In this case, nothing in the prosecution history indicates any deliberate disavowal of the claim scope by the inventors. Rather, the prosecution history demonstrates that the claim term was intended to establish a minimum dosage expressed as a creatine-to-body-weight ratio.

The claim at issue originated as claim 13 in the inventors' initial application for a patent for their creatine-related invention (which, as noted, covered both the method claimed in the 159 Patent and the composition claimed in the 544 Patent). That claim provided:

> A method to increase the muscle performance capability of mammals having no disorder in creatine metabolism, characterized by supplying enterally or perenterally a daily dosage of at least 15 g of creatine, or 0.2 - 0.4 g/kg body weight or preferably about 0.3 g/kg body weight.

Prosecution History at 125 (the "original claim"). The patent examiner rejected this claim on two grounds: its indefiniteness and its failure to enable its full purported scope. The examiner first noted that it was unclear which of the two ranges, "0.2-0.4 grams" or "about 0.3 grams," was controlling. As a separate basis of indefiniteness, the examiner noted that the claim did not specify, "under which circumstances 15 or more grams of creatine is to be administered, or 0.2-

0.4 grams/kg weight is to be administered." The examiner noted that this was a particular concern for a small mammal such as a "mouse or human infant" that could not tolerate a 15 gram dose of creatine. *Id.* at 196-197. Similarly, with respect to the scope of the claim, which in both the original claim and in the 159 Patent is "mammals having no disorder in creatine metabolism," the examiner noted that the claim as written enabled only "claims limited to 'reasonably sized mammals'" because the 15 gram dose would be incompatible with the alternate dosage of 0.2-0.4 grams of creatine per kilogram of body weight for small mammals. *Id.* at 197-198.

The inventors overcame the examiner's objections by replacing the original claim with the text that appears as Claim 1 in the 159 Patent and that is the subject of the instant dispute. *See* 159 Patent col.6 ll.19-25. In lieu of the original claim's three alternate doses, which were the basis of the examiner's first indefiniteness objection as to that claim, the revised claim contains a single creatine-to-body-weight ratio expressed as an unqualified minimum, "0.2 [grams of] creatine [per kilogram of] body weight," rather than as a range or approximate amount. To address the confusion generated by the first of the three alternate doses, "at least 15 [grams] of creatine," as well as the examiner's objection that this minimum dosage limited the claim's scope because it would be incompatible with small mammals, the inventors added the words "corresponding to" as a preface to this term and qualified it with "in a 70 kg mammal," thereby creating a creatine-to-body-weight ratio applicable to mammals of any weight. By placing this ratio after the first ratio and separating the two with the words "and not less than" rather than "or," the inventors created a conjunctive term setting forth two separate criteria for the creatine dosage to be administered under the patented method.

In explaining their modified claim, the inventors purported to have traversed the examiner's objection as to the original claim's scope limitation with respect to small mammals. *See* Prosecution History at 239. Had the inventors intended to disavow the claim with respect to small mammals, as Met-RX claims they did, they could have done so expressly by inserting a qualifier such as "reasonably sized" before "mammals."[7] That they instead qualified "fifteen grams" suggests that they elected to do that which they in fact did do with the revision at issue: create an unambiguous dosage of creatine to be administered to all mammals. The prosecution history thus reveals that the inventors added the words "corresponding to" in order to clarify that the term should be interpreted as a creatine-to-body-weight ratio and not as an absolute minimum dosage for a product to be used only by mammals of more than a certain minimum weight.

Finally, Met-RX argues that without the proposed weight restriction the claim is void for indefiniteness or for infringing on prior art. *See* MB at 14-15; MR at 6-7. By itself, the argument carries no weight, as a court is prohibited from reading limitations into a claim to preserve its validity. *See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.,* 849 F.2d 1430, 1434 (Fed. Cir. 1988) (citing *Sjolund v. Musland, Norsol, Inc. and Wink Corp.,* 847 F.2d 1573, 1582 (Fed. Cir. 1988)). Nonetheless, if a claim term remains ambiguous *after* the application of other claim construction principles, a court should at that point – and not before – choose the

---

[7] One might assume that the purpose of such a qualifier would be to overcome the examiner's objection and secure the requested patent. But what Met-RX does not explain is why the game would be worth the candle. It is far from obvious that 70 kilograms (or 154 pounds) marks the boundary between mammals that are, in the patent examiner's words, "reasonably sized," Patent History at 197, and those that are not. Nor can I conceive the benefit that the inventors might hope to achieve by securing a patent with such a weight limitation, given the great many people – potential customers, all – whom the examiner would apparently describe as "unreasonably small mammals."

construction that preserves the patent's validity. *See Philips v. AWH Corp.,* 415 F.3d 1303, 1327-1328 (Fed. Cir. 2005) (citing cases). Viewed in this light, Met-RX's appeal to preserving the validity of the patent held by its opponent can only succeed if Met-RX first demonstrates some residual ambiguity in the claim term. This it cannot do.

Met-RX essays to demonstrate the claim term's ambiguity in two different ways. First, it argues that without the weight restriction it proposes, the claim suffers from the same vagueness problem that the examiner found in the initial claim. The Prosecution History cannot support that theory. As discussed, the examiner's objections stemmed from two specific issues. First, he concluded that the original claim's reference to three alternate dosages, without any indication of the circumstances in which any one should be preferred to the others, rendered the claim too imprecise. Second, the examiner objected that the incompatibility of one of the three dosage descriptions with the use of the product in small mammals also created confusion. *See* Prosecution History at 196-197. The revised claim – that is, the claim now before the court – adopted plain language that cured both of those problems. Thus, whatever shortcoming Met-RX may find in the revised language, it is *not* the same problem that led the examiner to reject the original claim.

Next, Met-RX argues that unless the court interprets the claim's reference to a 70-kilogram mammal as a weight restriction, the patent will establish two inconsistent creatine-to-body-weight ratios – respectively, 0.2 grams and 0.214 grams per kilogram of body weight – as the minimum dosage under the patented method. MR at 6. It is true that the claim as written creates two different dosages, each of which is expressed as a creatine-to-body-weight ratio and each of which, when read independently, appears to prescribe a minimum dosage. However, it is

not true that the claim as written and the construction that OCPC advocates are "hopelessly indefinite" as to which of these two ratios should be used. MR at 6. Rather, because the two ratios are prescribed in the conjunctive, the higher one trumps the lower ratio that precedes it.

By way of illustration, for a 65-kilogram mammal, the minimum dosage of creatine using the first ratio would be 13 grams (0.2 grams per kilogram of body weight multiplied by 65 kilograms), whereas under the second ratio the minimum dosage would be 13.9 grams (.214 grams per kilogram of body weight multiplied by 65 kilograms). By listing the two ratios in the conjunctive, with the lesser creatine-to-body-weight ratio preceding the greater, the claim leaves no uncertainty that the latter, higher creatine-to-body-weight ratio is in fact the minimum dosage level described in the patented invention. *See* 159 Patent col.6 ll.23-25 ("at least 0.2 ... *and not less than*") (emphasis added).

To be sure, my reading of the disputed language – which I believe to be the natural interpretation of the claim term's unambiguous text – renders part of the claim language redundant: if the minimum dosage is 0.214 grams per kilogram of body weight, the claim would mean the same if it omitted the reference to the lower ratio of 0.2 grams per kilogram of body weight. But despite taking issue with that redundancy, Met-RX fails to propose an alternate reading that would eliminate it. Applying its proposed construction to the example of a 70-kilogram mammal, the result would be the same: under the first part of the claim, which Met-RX's proposal leaves unchanged, the minimum dosage of .2 grams per kilogram would be 14 grams, while the second portion of the claim ("not less than 15 [grams]") would require a minimum dosage equivalent to .214 grams per kilogram of body weight. *See* JCCS II at 3.

Thus, *neither* party proposes a construction that eliminates all redundancy from Claim 1 and that gives independent meaning to the first ratio. I cannot imagine any construction that could. But the existence of such redundancy is immaterial – for purposes of claim construction, at any rate, if not for purposes of determining the patent's validity – because the claim's language and other intrinsic evidence unambiguously conveys the inventors' intent with respect to the minimum dosage. The plain meaning of the claim is that the minimum dosage is "an amount corresponding to 15 grams in a 70-kilogram mammal" or .214 grams of creatine per kilogram of body weight. Therefore, the claim term "not less than an amount corresponding to 15 [grams of] creatine in a 70 [kilogram] mammal" requires no judicial construction beyond its plain terms.[8]

D. "Unitary Doses" (544 Patent, Claim 9)

OCPC argues that the disputed term in claim 9 of the 544 Patent, "unitary doses," has a plain and ordinary meaning that requires no construction. *See* OR at 24. Met-RX argues that the claim language and the intrinsic evidence compel the following construction: "10-20 grams of creatine composition that are individually packaged in sachets, bags, packets, cyclinders, bottles, or other suitable packages." MB at 21. I agree with Met-RX.

The crux of the dispute concerns the parties' very different interpretations of a specific portion of the specification that elaborates on the inventors' method for providing creatine in a powder form. By way of context, the portion of the specification in which the disputed discussion occurs – the "Summary of the Invention" – begins with an overview of the patented

[8] Because the intrinsic evidence is sufficient, I did not consider the evidence Met-RX submitted that the parties agree is extrinsic to the patent at issue. *See* DE 104 (Supplemental Declaration of Nathan E. Shafroth and attached documents concerning the prosecution of a related Australian patent); Transcript of Motion dated April 28, 2006 ("Tr.") at 3-7. The parties' dispute about the timeliness and relevance of that evidence is therefore moot.

composition and the first preferred embodiment of the composition: "a drink which is isotonic (i.e. corresponds to the osmotic potential of human body fluids) and/or comprises electrolytes." 544 Patent col.2 ll.35-38. The summary then discusses the second aspect of the invention: a method of storing the composition at "lower than ambient temperatures" to inhibit the conversion of creatine to creatinine.[9] *See id.* col.2 ll.53-62. The specification then addresses the provision of creatine in powder form, noting that the powder can be used with any suitable liquid and that "[w]hen provided as a powder, the composition may conveniently be packaged in conventional consumer packages (preferably hermetically sealed) such as foil sachets or pouches, tubes, tubs and the like." *Id.* col.3 ll.5-9. Next, the specification recites the inventors' method of supplying creatine in a powder form – a discussion that includes the following disputed description:

> Typically, the powder is such that, when a certain amount is dissolved in a pre-determined volume of water, it provides an isotonic drink. Desirably, the powder is provided as unitary doses (of about 10-20 grams) which may be dissolved in 200-350 mls of water to provide an isotonic drink. The unitary doses are conveniently supplied individually packaged in sachets, bags, packets, cylinders, bottles or other suitable packaging means. Preferably the package is hermetically sealed (e.g., a thin foil sachet) to prevent the ingress of water or water vapour.

Id. col.3 ll.21-30.

Met-RX contends that the quoted discussion explains the inventors' concept of "unitary doses." MB at 21-22. OCPC disagrees, and argues instead that the discussion's repeated use of such qualifiers as "typically," "desirably," and "preferably" evinces the inventors' intent that there

---

[9] Sadly (for lay persons like me), the preceding text is not a typographical error. Although creatine and creatinine are related both chemically and orthographically, they are in fact distinct compounds that differ in key respects. Specifically, creatine improves muscular performance and is stored in muscle tissue; however, in aqueous or acidic solutions, it converts into creatinine, which has no such effect on performance and is instead excreted as waste. 544 Patent col.2 ll.4-8. Thus, a critical aspect of the inventors' discovery is that it inhibits the conversion of creatine into creatinine and thereby preserves the former's bio-effectiveness. *See* OR at 3.

might be several different ways to supply a unitary dose, only one of which (albeit possibly the preferred method) would be to put 10-20 grams of the powder into an individual package. *See* OR at 24-25. As an example, OCPC claims that it would be consistent with the patent's reference to unitary doses to package a larger amount of uniformly blended powder in a container "with directions and a scoop for dispensing the dose" in measures of 10-20 grams. *Id.* at 25.

It is clear that the four sentences quoted above were intended to define the phrase "unitary doses" and that the court must therefore construe the term in light of that discussion. *See Philips*, 415 F.3d at 1316 ("In light of the statutory directive that the inventor provide a 'full' and 'exact' description of the claimed invention, the specification necessarily informs the proper construction of the claims.") (quoting 35 U.S. § 112, ¶ 1); *Kinik Co. v. Int'l Trade Comm'n*, 362 F.23 1359, 1365 (Fed. Cir. 2004) (words in claim terms "have the meaning and scope with which they are used in the specification and prosecution history"). A careful reading of that discussion indicates that the inventors intended that the unitary doses would be individually packaged. While *other* portions of the description contain prefatory qualifiers – such as "desirably" before the discussion of the provision of the powder as unitary doses and "preferably" before the words "hermetically sealed" – the sentence describing the means of supplying the "unitary doses" contains no such qualifier. Rather, the specification states unequivocally that the unitary doses "*are* conveniently supplied individually packaged in sachets, bags, packets, cylinders, bottles or other suitable packaging means." 544 Patent col.3 ll.26-28 (emphasis added).

I am assuredly not skilled in the art relevant to this litigation, but I am confident that anyone who is would conclude that the term "unitary doses," as it is used in the claim language, refers to individually *packaged* doses of approximately 10-20 grams rather than to a larger

container of powder that can simply be administered in such smaller doses. I therefore recommend that the court adopt the construction of that term that Met-RX proposes.

III. Conclusion

For the reasons set forth above, I respectfully recommend that the court adopt the following interpretations of the disputed claim terms of the patents at issue in this case:

- In claim 1 of the 159 Patent, as Met-RX contends, the term "suffering from or running a risk of depletion of muscle phosphoryl creatine storage" means "having reduced, or potentially reduced, phosphoryl creatine storage in muscle."

- In claim 1 of the 159 Patent, as OCPC contends, the term "not less than an amount corresponding to 15g creatine in a 70 kg mammal" requires no construction beyond its plain terms.

- In claim 9 of the 544 Patent, as Met-RX contends, the term "individual doses" means "10-20 grams of creatine composition that are individually packaged in sachets, bags, packets, cylinders, bottles, or other suitable packages."

IV. Objections

This Report and Recommendation will be filed electronically on the court's ECF system and is deemed served on all parties as of today's date. Any objections to this Report and Recommendation must be filed with the Clerk of the Court with a courtesy copy to me by September 5, 2006. Failure to file objections within this period waives the right to appeal the District Court's Order. *See* 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72; *Beverly v. Walker*, 118 F.3d 900, 902 (2d Cir. 1997); *Savoie v. Merchants Bank*, 84 F.2d 52, 60 (2d Cir. 1996).

SO ORDERED.

Dated: Brooklyn, New York
August 21, 2006

/s/ James Orenstein
JAMES ORENSTEIN
U.S. Magistrate Judge